

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

JESSE POLANSKY M.D., M.P.H., et al.	
v.	CIVIL ACTION
EXECUTIVE HEALTH RESOURCES, INC., et al.	NO. 12-CV-4239

FINAL MEMORANDUM

Baylson, J.

November 5, 2019

I. INTRODUCTION

Jesse Polansky (“Relator”) brings this False Claims Act qui tam¹ action on behalf of the United States alleging that Executive Health Resources, Inc. (“Defendant”) caused its client hospitals to fraudulently bill Medicare and Medicaid by falsely designating patient admissions as inpatient when they should have been marked as outpatient.

This case, which was filed over seven years ago, has an extensive procedural history. Presently before the Court is the Government’s Motion to Dismiss, as well as the briefs submitted by the parties following the Court’s Order of September 26, 2019, (ECF 550), invoking FED. R. Civ. P. 56(f) and giving notice of possible entry of summary judgment on other grounds.

¹ The False Claims Act was “originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War.” United States v. Bornstein, 423 U.S. 303, 309 (1976). The qui tam provision of the False Claims Act permits “a private person, known as a relator, ... [to bring an action] ‘for the person and for the United States Government ... in the name of the Government.’” Cochise Consultancy, Inc. v. Hunt, 139 S. Ct. 1507, 1510 (2019) (quoting 31 U.S.C. § 3730(b)).

II. BACKGROUND

A. Case History²

Relator filed his Complaint under seal on July 26, 2012 in accordance with the False Claims Act (“FCA”), 31 U.S.C. § 3729 et seq. (ECF 1.) Relator twice amended his Complaint, (ECF 9; ECF 12) before the Government declined to intervene on June 27, 2014, (ECF 19.) Thereafter, pursuant to the FCA, Relator served the then-operative Complaint on Defendant and proceedings commenced before the Honorable Thomas O’Neill, who issued an extensive Memorandum and Order denying the Defendant’s Motion to Dismiss on July 26, 2016. (ECF 103.) The following year, after Judge O’Neill’s death, the case was transferred to the undersigned. (ECF 141.)

The core of Relator’s theory of liability is that Defendant exploited the difference in reimbursement rates for inpatient and outpatient services,³ causing hundreds of thousands of claims for medical services to be billed as inpatient when they should have been billed as outpatient.⁴ It became obvious to the Court, and was not seriously contested by Relator or Defendant, that the best way to adjudicate this case was to hold a bellwether trial on a limited number of claims.⁵ Following multiple submissions and conferences, the Court entered an order

² Unless the name of the docket entry is relevant to this Memorandum, the Court will refer to docket entries solely by their assigned number.

³ According to Relator, “Medicare generally pays about \$4,500-\$5,000 more for inpatient services ... than it does when the same services are provided to a patient classified as outpatient observation.” (ECF 429, Ex. A., Third Am. Compl. ¶ 66) (“Third Am. Compl.”).

⁴ For a comprehensive description of the scheme, see *Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 484-88 (E.D. Pa. 2016) (O’Neill, J.). As summarized by Judge O’Neill, there are two potential levels of review for a physician’s initial determination of whether a patient should be classified as inpatient or outpatient. At the first level, a review is conducted by an internal hospital committee using standard industry criteria. *Id.* at 485. If the internal committee determines that a patient does not qualify for inpatient designation, many hospitals then have a physician advisor, such as Defendant, conduct a second level review. *Id.* After physician advisor review, the hospital—not the physician advisor—submits the claim for reimbursement to Medicare or Medicaid. (Am. Compl. ¶ 115.) Relator alleges that Defendant, as a physician advisor conducting second level reviews (i.e., reviewing the determination of the internal review committee that a patient does not qualify for inpatient status), “knowingly misconstrue[d] ... regulations when ... review[ing] hospital admission determinations, fraudulently certifying ‘thousands upon thousands of cases’ for hospitals to submit to Medicare and Medicaid as inpatient claims rather than outpatient as appropriate.” *Polansky*, 196 F. Supp. 3d at 485.

⁵ See generally MELISSA J. WHITNEY, BELLWETHER TRIALS IN MDL PROCEEDINGS: A GUIDE FOR TRANSFEREE JUDGES (2019).

requiring the parties to select a limited number of claims for discovery, following which a smaller number of claims would be selected for a bellwether trial. (ECF 240.) The Court eventually held that each party would select specified claims for itself and other claims would be chosen randomly for discovery. This procedure was designed to result in a jury trial where the jury would answer interrogatories as to whether Relator had proven Defendant violated the FCA by seeking and accepting improper reimbursements, and the Court would enter judgment on all other claims encompassed by the jury verdict after the bellwether trial.

For pretrial management, the case was divided into two segments. The first segment, “Phase I,” was designed to adjudicate reimbursement claims certified by Defendant from January 1, 2009 to October 1, 2013.⁶ The second segment, the “Two Midnight” phase, was designed to address Relator’s reimbursement claims for events that occurred after October 1, 2013, on which date the Centers for Medicare and Medicaid Services (“CMS”) implemented a new reimbursement regime—the Two Midnight Rule.⁷ In short, the Two Midnight Rule requires that, to admit an individual as an inpatient, the admitting physician expects that the patient’s stay will cross two midnights.⁸

Extensive discovery proceeded with several motions filed by both parties, which the Court attempted to resolve fairly and promptly.⁹ During the course of this discovery, Relator’s conduct

⁶ Relator seeks to prove liability for Phase 1 certifications that meet the following criteria:

“(a) For beneficiaries whose length of stay after the inpatient admission was (1) day or less; and

(b) The medical record does not demonstrate that there was a reasonable basis at the time of the inpatient order for the treating physician to expect a medically necessary hospital stay of 24 hours or longer.”

(Third Am. Compl. ¶¶ 364; 379.)

⁷ After a notice and comment period, CMS published the final version of the Two Midnight Rule on August 19, 2013, effective beginning October 1, 2013. Two Midnight Rule, 78 Fed. Reg. 50,496 (Aug. 19, 2013) (codified as amended 42 C.F.R. § 412.3(d)(1)).

⁸ The full Regulation reads: “[A]n inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.” 42 C.F.R. § 412.3(d)(1).

⁹ On February 21, 2019, the Court appointed a Special Master—Sandra Jeskie, an expert on electronically stored information (“ESI”)—to oversee discovery issues. (ECF 399.) The majority of discovery that has been conducted to date dealt with Relator’s Phase 1 claims, though some discovery has been taken on the Two Midnight claims as well.

interrupted the intended discovery; his behavior was material and plays a role in the final disposition of this case.

First, Relator belatedly revealed that he located a DVD disk in his personal possession containing approximately 14,000 documents. Relator testified about this discovery and the surrounding circumstances on January 15, 2019, (ECF 357), but the Court found that he was not completely credible. Relator's counsel admitted that a large number of the documents contained on the disk were relevant to Phase I. The unearthing of the disk caused a disruption in the proceedings. The Court allowed for discovery on the circumstances under which the DVD was found and why the documents on it, at least those relevant to this case, had not been turned over. Defendant subsequently moved for sanctions, which the Court granted in part. (ECF 400.)

Second, Relator unilaterally purported to change the settled method for selection of claims that had been painstakingly arrived at after several pretrial conferences without offering any explanation as to why he failed to seek court approval. This attempted change was never satisfactorily explained by Relator. See ECF 460, June 26, 2019 Memorandum at 2 (warning that Relator's actions "may have significance in future Court rulings in this case").¹⁰

These two events—the revelation of Relator's DVD disk and Relator's attempt to change the selection of cases for the bellwether trial—caused serious prejudice to Defendant and unnecessary delays in pretrial proceedings.

¹⁰ Dismissal of all or part of Relator's claims may be appropriate as a sanction for his conduct. The Third Circuit requires that a district court considering dismissal to sanction a discovery violation balance six factors: "(1) the extent of the party's personal responsibility; (2) the prejudice to the adversary caused by the failure to meet scheduling orders and respond to discovery; (3) a history of dilatoriness; (4) whether the conduct of the party or the attorney was willful or in bad faith; (5) the effectiveness of sanctions other than dismissal, which entails an analysis of alternative sanctions; and (6) the meritoriousness of the claim or defense." Poulis v. State Farm Fire & Cas. Co., 747 F.2d 863, 868 (3d Cir. 1984). The Court is not satisfied that the Poulis factors warrant dismissal.

B. Government's Notification of Intent to Seek Dismissal

On February 21, 2019—while the parties were litigating Defendant's sanctions motion—the Government notified Relator and Defendant via email that it intended to dismiss the case. (ECF 403, Ex. A.) The parties and the Government entered into negotiations directly, and without any involvement by the Court. On May 9, 2019, the Government notified the Court that it did not intend to exercise its dismissal authority, provided that Relator would proceed on claims under a significantly narrowed framework, and that it did not anticipate pursuing dismissal before the Court ruled on summary judgment motions. (ECF 430.) According to the Government, Relator's offer to narrow his claims "substantively and materially changed the ... cost/benefit analysis concerning the exercise of ... Section 3730(c)(2)(A) dismissal authority." (*Id.* at 4.) However, the Government noted that it intended to "reserve[] the right to evaluate whether dismissal is warranted in the future based on further developments, including arguments raised by the parties, further factual and evidentiary developments, and associated discovery burdens." (ECF 454 at 4.)

C. Third Amended Complaint

On May 2, 2019, Relator moved for leave to file a Third Amended Complaint, (ECF 429), that purported to adhere to the narrowing criteria the Government had agreed to. The Court ordered that the Third Amended Complaint, attached as Exhibit A to the Motion, be deemed filed as of May 10, 2019. (ECF 433.) The Third Amended Complaint is the operative complaint in this litigation.

Despite the previous indications that the Government and Relator concurred in the narrowing of Relator's claims, further events revealed that disagreements remained as to exactly what, if any, narrowing of the claims had taken place. This issue was never finally resolved. *See* ECF 543, Government Reply Memorandum at 7 ("[R]elator has dismissed no bellwether claims

and does not appear to have narrowed how he is pursuing this case.”); ECF 460 at 3 (identifying “at least one contradiction between Relator’s interpretation of the narrow[ing] criteria and the Government’s”); ECF 456, June 24, 2019 Hr’g Tr. at 11:22–23 (acknowledging that Polansky’s counsel’s view of the claims that would proceed was different from “the scope that the government is envisioning”). The divergence between the views of the Government and those of Relator regarding the extent to which Relator’s claims were narrowed suggests that the concerns underlying the Government’s intent to support dismissal in February are still present.

Several developments related to the merits of Relator’s claims and the parties’ respective discovery obligations occurring during the summer months leading up to the Government’s filing. The Special Master recommended that the Government produce, as confidential discovery material, “all documents withheld on the basis of the deliberate process privilege that are dated 2015 or earlier.” (ECF 510 at 6.) The Special Master also recommended the Government be required to produce responsive documents for additional custodians. (*Id.* at 9.) Finally, on August 7–8, 2019, Relator was deposed by Defendant. (ECF 540, Def. Memorandum in Supp. of Government Mot. to Dismiss at 8.) The Government participated in Relator’s deposition telephonically. (Government Reply Memorandum at 8.)

D. Government’s Renewed Motion to Dismiss

On August 20, 2019, the Government filed a Motion to Dismiss Relator’s Third Amended Complaint pursuant to its authority under 31 U.S.C. § 3730(c)(2)(A). (ECF 526.) Because the Court had previously set a dispositive motion deadline for August 30, 2019 (shortly after the Government’s filing), all discovery and other dates were stayed pending the Court’s resolution of the Government’s Motion. (ECF 529.) On September 6, 2019, Relator filed a response in opposition to the Government’s Motion to Dismiss. (ECF 533.) On September 13, 2019,

Defendant filed a memorandum in support of the Government's right to seek dismissal of the case. (ECF 540.) The Government filed a reply memorandum on September 17, 2019. (ECF 543.) The Court scheduled oral argument for September 25, 2019 and transmitted to the parties a list of questions to be discussed at the hearing. (ECF 544; ECF 547.)

The day after the hearing, on September 26, 2019, the Court invoked FED. R. CIV. P. 56(f), ordering Relator and Defendant to submit briefs addressing the applicability of two recent Supreme Court decisions¹¹ and allowing the Government to file a brief limited to its view of the substantive merits of Relator's claims as they relate to the decision to seek dismissal. (ECF 550.) The Government filed its supplemental brief on October 11, 2019, (ECF 554), as did Relator, (ECF 555), and Defendant, (ECF 556.)

III. DISCUSSION

The Discussion will proceed as follows. First, in Part III.A, the Court discusses the split of authority on the standard of review applicable to 31 U.S.C. § 3730(c)(2)(A) and concludes that because the Government's decision to dismiss is sufficiently reasoned and supported, the Government is entitled to dismissal under either the rational relationship test or the unfettered discretion test.

Second, in Part III.B, the Court articulates additional reasons that support dismissal, independent of the Government's motion. As to the Phase 1 claims, the Court concludes that summary judgment is proper because the 24-hour policy—the time-based reimbursement standard prior to implementation of the Two Midnight Rule—did not go through notice and comment rulemaking procedures, as required by the Medicare Act. As to the Two Midnight claims, the Court notes, without deciding, that summary judgment may be proper because Relator has not

¹¹ Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019); Universal Health Servs., Inc. v. Escobar, 136 S. Ct. 1989 (2016).

established Defendant's alleged misconduct was "material" to the Government's reimbursement decision.

At oral argument on September 25, 2019 and reiterated in their post-hearing memoranda, both the Government and Defendant strenuously objected to the Court deciding whether to grant summary judgment in addition to or instead of granting the Government's Motion to Dismiss. See, e.g., ECF 554, Government Suppl. Memorandum in Supp. of Mot. to Dismiss Relator's Third Am. Compl. at 1 ("Government Suppl. Memorandum"); ECF 552, Sept. 25, 2019 Hr'g Tr. 45:19-21. Given the many years of work that have gone into this case, it is appropriate to document findings and conclusions on the other issues raised.¹² Although rare, it is not unprecedented for a court to consider a Section 3730(c)(2)(A) dismissal motion at the same time as summary judgment arguments. See, e.g., Stierli v. Shasta Servs. Inc., 440 F. Supp. 2d 1108, 1109 (E.D. Cal. 2006) (granting government motion to dismiss after hearing argument on Section 3730(c)(2)(A) motion and cross motions for summary judgment filed by Relator and defendant); see also Stierli v. Shasta Servs. Inc., No. 2:04-cv-1955-MCE-PAN (E.D. Cal. May 22, 2006), ECF 68, Minute Order (noting that government motion to dismiss and cross claims for summary judgment would be heard in one hearing).

Moreover, the Third Circuit has acknowledged that "[i]t is well-settled that [FED. R. CIV. P. 56(f) permits] district courts [to] grant summary judgment sua sponte, so long as the losing party is given notice when summary judgment is being contemplated." Forrest v. Parry, 930 F.3d 93, 110-11 (3d Cir. 2019). The Court gave ample notice to the parties in the September 26, 2019

¹² This approach also ensures that, if Relator takes appeal, the other issues the Court considers dispositive will be before the Third Circuit. Therefore, if the Third Circuit disagrees with the Court's Section 3730(c)(2)(A) analysis, there is an alternative rationale that will permit that court to affirm. See Sept. 25, 2019 Hr'g Tr. 19:13- ("[I]f [the Court] were to ... grant the motion to dismiss ... that leaves the merits of the case completely undecided, and if the Third Circuit or eventually the Supreme Court were to take this case and either of them were to decide that I erred in dismissing it, then it's going to come back and then I've got to return to the merits.").

Order of the possibility that it would consider summary judgment based on the two recent Supreme Court cases and permitted supplemental briefing on the additional issues. Therefore, the Court’s consideration of summary judgment on these questions is proper.

A. Government Dismissal under 31 U.S.C. § 3730(c)(2)(A)

1. Statutory Authority for Government Dismissal

The False Claims Act imposes liability on anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim [to the United States] for payment or approval.” 31 U.S.C. §§ 3729(a)(1)(A); 3729(b)(2). The FCA is unique because it permits a private person—a “relator”—to litigate the action if the government declines to intervene. *Id.* § 3730(b)(1). The FCA incentivizes relators by guaranteeing financial compensation; the amount of compensation varies depending on whether the Government intervenes. *Id.* § 3730(d)(1)–(2).

While the FCA permits a relator to proceed on a claim the Government declines to prosecute, the government, as the injured party and ultimate beneficiary of any recovery that results, retains authority to exercise control over the litigation. Under 31 U.S.C. § 3730(c)(2)(A), the Government has the right to dismiss a qui tam action “notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.”¹³

¹³ In January 2018, Michael Granston, Director of the Commercial Litigation Branch, Fraud Section of the Department of Justice (“DOJ”), issued an internal memo (later incorporated into the DOJ Justice Manual) encouraging government attorneys to use the Government’s Section 3730(c)(2)(A) dismissal power, as “it remains an important tool to advance the government’s interests, preserve limited resources, and avoid adverse precedent.” Memorandum from Michael Granston, Dir., Fraud Section of Commercial Litig. Branch of DOJ, to All Attorneys in Commercial Litig., Branch, Fraud Section at 2 (Jan. 10, 2018). The memo explicates seven nonexhaustive factors that DOJ attorneys should consider in deciding whether to move to dismiss: curbing meritless cases, preventing parasitic or opportunistic qui tam actions, preventing interference with agency policies and programs, controlling litigation brought on behalf of the United States, safeguarding classified information and national security interests, preserving government resources, and addressing egregious procedural errors. *Id.* at 3-7.

Although Section 3730(c)(2)(A) establishes the Government’s authority to dismiss a qui tam action, the FCA does not explicate a standard of review for courts to apply to Government dismissal motions. This is in contrast to other provisions of the FCA that both reserve certain rights to the Government and set forth the standard that the court should use. See, e.g., id. § 3730(c)(2)(B) (“The Government may settle the action notwithstanding the objections of the [relator] if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances.”). The FCA’s apparent silence on the standard applicable to Section 3730(c)(2)(A) has led to a circuit split, with the Ninth and Tenth Circuits taking the rational relationship approach and the District of Columbia Circuit adopting the unfettered discretion test.

2. Circuit Split on Standard of Review Applicable to Government Dismissal

Appellate courts have adopted two different standards for assessing government dismissal under Section 3730(c)(2)(A): (a) the Ninth and Tenth Circuits have adopted the slightly more rigorous rational relationship test;¹⁴ and (b) the District of Columbia Circuit has adopted the unfettered discretion test. The Third Circuit has expressly declined to take a side in this circuit split. Two district court judges in the Eastern District of Pennsylvania have opined on how to analyze a government motion to dismiss a declined qui tam action.

a. Ninth and Tenth Circuit “Rational Relationship” Test [Sequoia]

Under the Ninth and Tenth Circuit’s rational relationship approach, a two-step analysis is used to test the government’s justification for dismissal under Section 3730(c)(2)(A). Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139 (9th Cir. 1998). This test requires that

¹⁴ The Second Circuit has also cited the rational relationship standard favorably. See Stevens v. State of Vt. Agency of Nat. Res., 162 F.3d 195, 201 (2d Cir. 1998), rev’d on other grounds, 529 U.S. 765 (2000) (citing Sequoia [the Ninth Circuit’s formulation of the rational relationship test] for the proposition that “[t]he government is ... given ample authority ... to bring [FCA qui tam] litigation to an early end.”).

the government identify (1) a valid government purpose supporting dismissal; and (2) a rational relation between dismissal and accomplishment of the asserted purpose. Id. at 1145. If the Government satisfies both elements of the rational relationship test, then the burden shifts to the relator “to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal.” Id. (internal quotations omitted).

The Sequoia court found that the two-step rational relationship approach best “respected the Executive Branch’s prosecutorial authority by requiring no greater justification of the dismissal motion than is mandated by the Constitution itself.” Id. at 1146. The Tenth Circuit adopted the Sequoia test on a similar rationale. See Ridenour v. Kaiser-Hill Co., LLC, 397 F.3d 925, 935 (10th Cir. 2005) (concluding that Sequoia “recognizes the constitutional prerogative of the Government under the Take Care Clause, comports with legislative history, and protects the rights of relators to judicial review of a government motion to dismiss”).

The Sequoia test is not intended to be rigorous—it does not require a “tight fitting relationship” between the purpose and accomplishment of the identified purpose. Sequoia Orange Co. v. Sunland Packing House Co., 912 F. Supp. 1325, 1341 (E.D. Cal. 1995). Rather, the Government’s burden is simply to set forth a rational reason supporting its decision to seek dismissal; once it does so, “it becomes the relator’s burden to come forward with some evidence to rebut the Government’s asserted reasons and demonstrate that the decision is fraudulent, arbitrary and capricious, or illegal.” Nasuti v. Savage Farms, Inc., No. 12-30121, 2014 WL 1327015, at *12 (D. Mass. Mar. 27, 2014).

b. District of Columbia Circuit “Unfettered Discretion” Test [Swift]

Following the Ninth Circuit’s adoption of the rational relationship test, the District of Columbia Circuit considered the appropriate standard to assess government motions to dismiss

under Section 3730(c)(2)(A) and concluded that Sequoia inappropriately impeded on the province of the executive. Swift v. United States, 318 F.3d 250, 251 (D.C. Cir. 2003). Rather, in the view of the Swift court, Section 3730(c)(2)(A) gives the “government an unfettered right to dismiss an action.” Id. (emphasis added). Swift provided two rationales for the highly discretionary standard it adopted. First, focusing closely on the statutory text, the court noted that the absence of a reference to the judiciary in Section 3730(c)(2)(A) “at least suggests the absence of judicial constraint.” Id. Second, according to Swift, the presumption of unreviewability that applies to initial government decisions not to prosecute counsels in favor of minimal judicial oversight of Section 3730(c)(2)(A) dismissals, because a government motion under this section essentially amounts to a decision not to prosecute. Id. Swift also noted that the purpose of Section 3730(c)(2)(A)’s guarantee of a hearing is “simply to give the relator a formal opportunity to convince the government not to end the case;” the section is not intended to invite judicial review of the government’s decision. Id. at 253.

c. Third Circuit and Eastern District of Pennsylvania Precedent

The Third Circuit noted the circuit split on the standard applicable to Section 3730(c)(2)(A) in two recent opinions but expressly declined to take a position. See Bookwalter v. UPMC, 938 F.3d 397, 417 (3d Cir. 2019) (“[O]ur Court has not yet specified the standard of review for a [Section] 3730(c)(2)(A) dismissal”); Chang v. Children’s Advocacy Ctr. of Del., 938 F.3d 384, 387 (3d Cir. 2019) (“We need not take a side in the [Ninth/Tenth v. District of Columbia] circuit split because [relator] fails even the more restrictive standard.”).

The two district court judges in the Eastern District of Pennsylvania to squarely confront the question of which test (rational relationship or unfettered discretion) should apply have taken slightly different approaches.

Judge Stengel declined to “predict which standard the Third Circuit would adopt” in Surdovel v. Digirad Imaging Solutions, No. 07-0458, 2013 WL 6178987 (E.D. Pa. Nov. 25, 2013), concluding instead that the government satisfied both standards. Id. at *3.

Judge Savage took a different approach in SMSPF, LLC v. EMD Serono, Inc., 370 F. Supp. 3d 483 (E.D. Pa. 2019), finding that “the reasoning of the Ninth and Tenth Circuits [adopting the rational relationship test] is more persuasive than that of the District of Columbia Circuit [because it] accords with statutory interpretation and fosters transparency” and therefore adopting the Sequoia test. Id. at 488. Serono emphasized separation of powers considerations, because “[r]equiring some justification, no matter how insubstantial, for a decision not to pursue a false claim, acts as a check against the Executive.” Id. at 488-89. The Serono court ultimately concluded that the rational relationship test espoused by Sequoia appropriately balanced the interest of “the Executive [in] dismiss[ing] a legitimate action the Legislature created” against the interest of the judiciary in adjudicating disputes. Id. at 489.

3. Parties’ Arguments

The Government advocates for application of the unfettered discretion test, arguing that greater deference is more consistent with the other provisions of the FCA and well-accepted respect for prosecutorial discretion. (ECF 526, Government Mot. to Dismiss at 13.) Even if the Court applies the rational relationship test, argues the Government, a rational relationship between dismissal and a valid purpose has been shown because the Government articulated legitimate costs and demands that have been imposed by the litigation. (Id. at 18-20.) The costs considered in the Government’s decision to dismiss include the significant litigation burden, monitoring costs, discovery demands resulting from subpoenas and document requests, and required disclosure of information the Government views as privileged. (Id. at 18-19.)

Defendant's memorandum in support of the Government's motion echoes the Government's position that its decision to seek dismissal satisfies both the rational relationship and the unfettered discretion tests. (Def. Memorandum in Supp. of Government Mot. to Dismiss at 1-2.) Defendant also highlights the significant developments in the litigation that preceded the Government's filing, purporting to undermine Relator's contention that the Government's dismissal decision is not entitled to deference because the analysis of costs and benefits has not changed since May 9, 2019 when the Government indicated that it did not intend to use its Section 3730(c)(2)(A) authority. (*Id.* at 3-9.)

In opposition to the Government's motion, Relator argues that Sequoia is the proper standard to apply, because it appropriately balances deference with the need to ensure a backstop against arbitrary decisionmaking. (ECF 534, Relator Opp'n to Government Mot. to Dismiss at 5.) Applying this standard, according to Relator, the Government's motion fails because dismissal is not a rational response to the developments that occurred after May 9, 2019, the date on which the Government notified the Court that it did not intend to exercise its dismissal authority; and because the Government's reversal on its May 9, 2019 decision not to dismiss is arbitrary. (*Id.* at 10-17.)

4. Analysis

The Court need not decide whether the Sequoia rational relationship standard or the Swift unfettered discretion standard applies, because under either the Government is entitled to dismissal. Since Sequoia is slightly more demanding, the Court will apply that analysis to the Government's motion.

Under the two-step framework set forth in Sequoia, the Government must articulate a valid purpose supporting its decision to seek dismissal and explain how dismissal accomplishes that

interest. 151 F. 3d at 1145. If the Government establishes both elements, the burden shifts to the Relator to show the Government's decision is fraudulent, arbitrary and capricious, or illegal. Id.

In this case, the Government's decision to seek dismissal is based on its determination that the litigation burden imposed by Relator's case is no longer justified, and dismissal is rationally related to that interest because complete dismissal will eliminate the burden. Further, Relator has failed to show that the Government's decision is arbitrary or capricious.

a. Government Has Shown Preserving Litigation Resources is Rationally Related to Dismissal, in Satisfaction of Sequoia

Sequoia itself recognized that preserving litigation resources is a valid purpose under Section 3730(c)(2)(A). See id. at 1146 (“[T]he government can legitimately consider the burden imposed on the taxpayers by its litigation, [and can consider] that, even if the relators were to litigate the FCA claims, the government would continue to incur enormous staff costs.”). Lower courts applying Sequoia where the government claimed an interest in controlling litigation expenses have required legitimate investigation into the costs and benefits of continued litigation before granting a government motion to dismiss. See, e.g., CIMZNHCA, LLC v. UCB, Inc., No. 17-765, 2019 WL 1598109, at *3 (S.D. Ill. Apr. 15, 2019) (applying Sequoia and finding it not satisfied because the government “failed to fully investigate the allegations against the specific defendants in this case”); United States v. Acad. Mortg. Corp., No. 16-2120, 2018 WL 4794231, at *4 (N.D. Cal. Oct. 3, 2018) (“Relator’s evidence indicating that the Government may not have investigated the amended complaint at all, together with the Government’s failure to submit any responsive evidence, means that the Government failed to meet the Sequoia Orange rational relation standard.”). In this case, the Court is satisfied that the Government has thoroughly investigated the costs and benefits of allowing Relator’s case to proceed and has come to a valid conclusion based on the results of its investigation.

On the benefits side of the ledger, Relator attempts to cast doubt on the thoroughness of the Government's investigation by asserting that "the Government is leaving billions of dollars of potential recovery on the table." (Relator Opp'n to Government Mot. to Dismiss at 9.) Relator's theory does not persuade the Court. First, assuming arguendo the accuracy of Relator's position, Sequoia and Ridenour make clear that "the potential merit of a qui tam action is insufficient to overcome the government's rational reasons for dismissing the suit." Wickliffe v. EMC Corp., 473 F. App'x 849, 854 (10th Cir. 2012). Second, the veracity of Relator's argument is undermined by his failure to explain why the narrowing of the universe of claims does not diminish the scope of expected recovery. See Government Reply Memorandum at 6 n.1 ("[I]f [R]elator truly narrowed his case, it is unclear how he still views his case to be worth 'billions of dollars.'") Third, Relator's bold assertion does not address the likelihood that the potential benefits he highlights will be realized. To the contrary, the Government cites genuine concerns regarding the likelihood that Relator will successfully establish FCA liability, including his inability to access "medical records to determine whether all of the narrowed bellwether claims are false;" his failure to demonstrate that Defendant "caused the submission of false claims to CMS following implementation of the Two Midnight Rule;" and his credibility given prior behavior in this case. (Government Mot. to Dismiss at 21.) Assessing the potential financial recovery highlighted by Relator (which, as noted, may not be as large as Relator claims given the narrowing of his claims) in the context of the likelihood for Relator's success indicates that the benefits are not as compelling as Relator asserts.

On the costs side of the ledger, the Government highlights legitimate burdens that it will face if this case is permitted to continue. The costs of continued litigation emphasized by the Government are akin to costs asserted in other FCA cases that, significantly, other courts have

accepted. For example, in Nicholson v. Spigelman, No. 10-3361, 2011 WL 2683161 (N.D. Ill. July 8, 2011), the Government identified the burdens of monitoring the case, filing briefs, responding to discovery requests, and preparing government officials for depositions as costs associated with allowing the litigation to continue. Id. at 2. The Nicholson court found that these costs satisfied Sequoia because they provided a “plausible, or arguable reason for dismissal.” Id. Similarly, in Health Choice All. LLC v. Eli Lilly & Co., Inc., No. 17-123, 2019 WL 4727422 (E.D. Tex. Sept. 27, 2019), the Government justified its decision to seek dismissal by reference to costs associated with monitoring the litigation, preparing agency witnesses for depositions, and defending depositions. Id. at *7. Health Choice found that these costs easily satisfied Sequoia’s requirements because dismissal would reduce the burdens the Government highlighted. Id. Finally, in Borzilleri v. Bayer Healthcare Pharmaceuticals, Inc., No. 14-31, 2019 WL 5310209 (D.R.I. Oct. 21, 2019), dismissal was granted on the government’s motion because they articulated a legitimate burden that continuing litigation would impose—a widespread inquiry involving multiple federal agencies. Id. at *2.

These cases only scratch the surface of the abundant case law granting dismissal to the government because of documented litigation costs, further reinforcing the view that even Sequoia “defer[s] a great deal to the Justice Department.” Bookwalter, 938 F.3d at 417; see, e.g., Stovall v. Webster Univ., No. 15-3530, 2018 WL 3756888, at *3 (D.S.C. Aug. 8, 2018) (holding that the government was entitled to dismissal because it demonstrated that “dismissal [would] further its interest in preserving scarce resources by avoiding the time and expense necessary to monitor this action”); Lion Raisins, Inc. v. Kagawa, No. 02-5665, 2003 WL 27387421, at *5 (E.D. Cal. Nov. 3, 2003) (“The Government may seek dismissal of an FCA claim on the grounds that the costs of pursuing the case would outweigh the benefits of recovery.”); Sequoia Orange, 912 F. Supp. at

1346 (finding that because “the government concluded that expenditure of the extensive resources required to continue prosecution and defense ... was disproportionate to the benefits obtainable” the government satisfied its burden under Sequoia).

The costs highlighted by the Government in this case are identical to those credited by Nicholson, Health Choice, and Borzilleri. The Government cites the following costs in support of its motion: the internal staff obligations that have been imposed and will continue to be imposed if litigation is permitted to continue;¹⁵ anticipated costs related to the document production recommended by the Special Master;¹⁶ expected attorney time associated with preparing depositions of CMS personnel¹⁷ and monitoring the litigation, including filing statements of interest; and the concern that material it deems as privileged has been produced and will be used.

Because it is well-accepted that “[t]he [G]overnment has an interest in minimizing unnecessary or burdensome litigation costs,” and because the Government has adequately documented why the costs outweigh the benefits of continued litigation, the Government has articulated a valid government purpose. Chang, 938 F.3d at 387. Clearly, dismissal would serve this purpose, because disposing of the case would alleviate the burdens that the Government objects to. Therefore, the Government has satisfied its burden under Sequoia and is entitled to

¹⁵ The declaration of Janet Nolan, the Deputy Associate General Counsel for the Program Integrity Group of the Office of General Counsel for the Department of Health and Human Services (“HHS-OGC”), helps to quantify the burden. (Government Reply Memorandum, Ex. 2) (“Nolan Decl.”) Nolan declares that of the six attorneys in her group dedicated full time to FCA litigation, two have been assigned to Relator’s case nearly exclusively. (Id. ¶¶ 3, 5-10.) Nolan describes how continued litigation will burden her office and may require reallocation of resources, which would take attorneys away from other matters that are of higher priority. (Id. ¶ 17.) The Government notes that in addition to the two HHS-OGC attorneys dedicated full time to this litigation described in Nolan’s declaration, the DOJ has assigned four attorneys to Relator’s claims, (Government Mot. to Dismiss at 10), and the Civil Division DOJ attorneys have logged over 1,500 hours of work in this case. (Government Reply Memorandum at 11 n.4.)

¹⁶ Nolan declares that if the Court were to adopt the Special Master’s recommendation on the scope of additional production, she anticipates the search for documents would require 100 attorney hours for three custodians, for a total of 300 hours. (Nolan Decl. ¶ 16(a).) This would mean that one-third of the lawyers in her group who are dedicated to FCA work full time would spend approximately one month solely working on this document review. (Id.)

¹⁷ Nolan declares that one of the attorneys assigned full time to this case would prepare and represent the depositions, but that the task may also require assigning other personnel. (Id. ¶ 18.)

dismissal unless Relator can demonstrate that the Government's decision is fraudulent, arbitrary and capricious, or illegal.

b. Relator Fails to Demonstrate Arbitrariness of Government's Decision

Since the Government satisfied its burden Sequoia, dismissal is appropriate unless Relator can establish that the Government's decision is fraudulent, arbitrary and capricious, or illegal. Sequoia, 151 F.3d at 1145. Relator fails to carry his burden, because he disregards the recent developments in this case and the effect they had on the Government's decision to seek dismissal.

Relator argues that the costs identified by the Government in moving to exercise its dismissal authority predated the Government's May 9, 2019 representation to the Court that it would not seek dismissal, so they cannot serve as a valid rationale. (Relator Opp'n to Government Mot. to Dismiss at 9.) However, this argument misses the mark, because it ignores the significant, and important, developments that occurred in this case between May 9, 2019 (when the Government indicated it did not intend to exercise its dismissal authority) and August 20, 2019 (when the Government filed the instant motion).

First, Relator failed to narrow the universe of his claims in the way he had promised. The Government unambiguously qualified its decision not to seek dismissal on the condition that Relator narrow his theory of the case. See ECF 430, Government Resp. to Relator's Mot. for Leave to File Third Am. Compl. at 1 ("[T]he United States ... will not exercise its authority under 31 U.S.C. § 3730(c)(2)(A) to dismiss the Relator's claims that meet the [narrowing] criteria."). However, because Relator has not narrowed his case, the concerns motivating the Government's prior consideration of whether to exercise dismissal authority remain and support the Government's motion. See Government Reply Memorandum at 7 ("To date, [R]elator has

dismissed no bellwether claims and does not appear to have narrowed how he is pursuing this case.”).

Second, the Government participated telephonically in Relator’s August 7–8, 2019 deposition. (Government Reply Memorandum at 8.) Information learned during this deposition was considered in evaluating dismissal and evidently changed the Government’s calculation. (Id.)

Third, the Special Master made two discovery recommendations that may have altered the Government’s assessment of the burdens associated with this case. The Special Master recommended that the Government produce documents it deemed as privileged (and had litigated to protect). (ECF 510 at 6.) The Special Master also recommended that the Government produce responsive documents for additional custodians, (id. at 9), which, if ordered, would require a substantial commitment of staff. (Nolan Decl. ¶ 16(a).)

Although the Government declined to exercise its dismissal authority on May 9, 2019, that decision was based on circumstances as they existed on that date. Indeed, the Government apprised the Court and the parties of its intent to continue to monitor the case, leaving open the possibility that Section 3730(c)(2)(A) could be invoked if the state of affairs materially changed. The Government was entitled to consider the developments that occurred from May 9, 2019 to August 20, 2019 in its decision to dismiss, as these events changed the status quo of this litigation.

In sum, the developments that occurred after the Government declined to exercise its authority to dismiss, as well as the Government’s continued concern about the litigation burden imposed by this case, refute Relator’s contention that the Government’s dismissal decision is arbitrary. To the contrary, the Government’s rationale appears to be well-reasoned and supported.

The history of this case, particularly the Government’s reversal on whether it intended to exercise its dismissal authority, is somewhat unusual. However, the Court has no reason to doubt

the integrity of the Government's present contention that allowing Relator's claims to move forward will impose an unjustified burden on the DOJ, CMS, and HHS. The Government has sufficiently documented its investigation into the costs and benefits of continued litigation, and has adequately shown a relation between its interest in preserving litigation resources and dismissal. Because the Government's motion to dismiss satisfies Sequoia's rational relationship test, it satisfies Swift's even more deferential unfettered discretion test. See Nasuti, 2014 WL 1327015, at *1 (granting government's motion to dismiss because both Swift and Sequoia standards were fulfilled). Therefore, if the Third Circuit has occasion to consider the proper standard to apply to Section 3730(c)(2)(A), then regardless of which approach the circuit chooses to adopt, the Government's motion to dismiss Relator's claims in this case is properly granted.

B. Summary Judgment Independent of Government Dismissal

Although the Court is granting the Government's Motion to Dismiss, the Court will discuss additional reasons that support dismissal of this case. As noted, the Court feels it is imperative to memorialize conclusions and findings on issues additional to the Government's Section 3730(c)(2)(A) motion, given the extensive history and briefing on these issues.

Subsection III.B.1 will discuss FED. R. CIV. P. 56 and the standard that the Court applies to the summary judgment arguments. Subsection III.B.2 will articulate why summary judgment is properly granted on the Phase 1 claims (i.e., those claims that arose before October 1, 2013) based on the rationale of the Supreme Court's recent decision in Azar v. Allina Health Services, 139 S. Ct. 1804 (2019) interpreting the notice and comment provision of the Medicare Act. Subsection III.B.3 will explain why summary judgment may be proper on the Phase 1 and Two Midnight claims based on the likelihood that Relator will not be able to establish that Defendant's alleged misconduct was material to the Government's payment decision.

1. Standard of Review Applicable to Summary Judgment

Summary judgment is proper if the movant can establish “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a). A dispute is genuine—and will preclude a grant of summary judgment—if “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). If a fact “might affect the outcome of the suit under the governing law,” the factual dispute is material and will allow the nonmovant to survive summary judgment. Id. Only if “the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party” is a grant of summary judgment appropriate. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). At the summary judgment stage, the district court is obligated to “review the record as a whole and in the light most favorable to the nonmovant, drawing reasonable inferences in its favor.” In re Chocolate Confectionary Antitrust Litig., 801 F.3d 383, 396 (3d Cir. 2015).

It is the responsibility of the litigant seeking summary judgment to inform the district court of the basis for its motion and identify the portions of the record that demonstrate the absence of a genuine dispute of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Where the burden of proof on a particular issue rests with the nonmoving party at trial, the moving party’s initial burden can be met by simply “pointing out to the district court that there is an absence of evidence to support the nonmoving party’s case.” Id. at 325. Once the moving party has met its initial burden, the nonmoving party must set forth specific facts—through citation to affidavits, depositions, discovery documents, or other evidence—demonstrating the existence of a genuine triable dispute. FED. R. CIV. P. 56(c).

2. Under Allina, CMS Failure to Promulgate 24-Hour Policy Pursuant to Notice and Comment Rulemaking, As Required by the Medicare Act, Warrants Summary Judgment as to Phase 1 Claims

Summary judgment in favor of Defendant is properly granted on Relator's Phase 1 claims because CMS's time-based reimbursement criteria is a "substantive legal standard" under the Medicare Act that did not receive notice and comment, as required by Allina's interpretation of the Medicare Act.

The core of the Allina decision as it relates to this case is that because the reimbursement standard applicable to the Phase 1 claims was contained in agency manuals that had not been promulgated pursuant to notice and comment, as required by the Medicare Act, Defendant could not have violated the FCA. To appreciate the significance of Allina and its applicability to this case, it is necessary to first understand the regulatory landscape and the history of CMS reimbursement guidance prior to implementation of the Two Midnight Rule.

a. Regulatory Landscape

Relator's claim implicates two related federal schemes: the False Claims Act and the Medicare Act. The FCA imposes liability for the knowing submission of false claims. The standards in the Medicare Act explain when a claim is false; and specify when notice and comment rulemaking is required. The Court will briefly summarize both schemes, and where they intersect, to situate the Allina analysis.

FCA: FCA liability attaches when a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). There are two categories of FCA falsity—factual falsity and legal falsity. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011). Of these two categories, legally falsity is at issue in this case. See Polansky, 196 F. Supp. 3d at 499 ("Relator primarily relies on a theory of legal falsity

to allege liability.”). A claim is legally false “when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment.” Wilkins, 659 F.3d at 305.

Medicare Act: This case implicates two functions of the Medicare Act. First, the Act sets parameters for reimbursement of Medicare claims, requiring that a service be “reasonable and necessary for the diagnosis or treatment of illness or injury” to qualify for reimbursement. 42 U.S.C. § 1395y(a)(1)(A) (emphasis added). The guidance discussed infra provides principles that aid providers in complying with the statutory requirement that services be “reasonable and necessary,” because that term is not defined in the Medicare Act. Second, and unrelated to the reimbursement regime, the Medicare Act requires that CMS provide the public with advance notice and an opportunity to comment before adopting a “rule, requirement, or other statement of policy ... that establishes or changes a substantive legal standard.” 42 U.S.C. § 1395hh(a)(2). This notice and comment provision was adopted as an amendment to the Medicare Act in 1987.

The Intersection of the FCA and the Medicare Act: The FCA and the Medicare Act interlock because a claim for services that are not “reasonable and necessary” under the Medicare Act is a legally false claim under the FCA, as the claim, by definition, does not comply with the statutory requirement for payment. In other words, if Defendant caused its client hospitals to seek reimbursement for services that were not “reasonable and necessary,” there could be FCA liability, because the claim did not comply with the payment conditions of the Medicare Act. CMS guidance expressed in manuals explains how to apply the Medicare Act’s “reasonable and necessary” requirement in the context of claim reimbursement.

b. CMS Reimbursement Guidance Prior to Implementation of Two Midnight Rule

Prior to adoption of the Two Midnight Rule, CMS provided guidance to help healthcare providers determine inpatient status for purposes of seeking reimbursement under the Medicare Act. This guidance operationalizes the statutory “reasonable and necessary” requirement of the Medicare Act in the context of hospital claims for reimbursement. The timeline of the guidance is as follows:¹⁸

- **Health Insurance for the Aged Hospital Manual (1968) § 210 (“1968 Manual”):** “A person is considered an inpatient if formally admitted as an inpatient with the expectation that he will remain at least overnight and occupy a bed even though it later develops that he can be discharged, or is transferred to another hospital and does not actually use a hospital bed overnight.”
- **Medicare Hospital Manual (1981) § 210 (“1981 Manual”):** “When a patient with a known diagnosis enters a hospital for a specific minor surgical procedure or other treatment that is expected to keep him in the hospital for only a few hours (less than 24), and this expectation is realized, he will be considered an outpatient regardless of: the hour of admission; whether or not he used a bed; and whether or not he remained in the hospital past midnight.”
- **Medicare Hospital Manual (1989) § 210 (“1989 Manual”):** “The physician should use a 24-hour period as a benchmark, i.e., he or she should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis.”

In summary, prior to implementation of the Two Midnight Rule on October 1, 2013, CMS’s manuals recommended a time-based framework to determine eligibility for inpatient status. The 1981 Manual introduced the concept of a 24-hour standard, and the 1989 Manual clearly instructed that a 24-hour period be used as a benchmark (the “24-hour policy”). None of these policies went through notice and comment rulemaking; they were merely conveyed in manual guidance.

¹⁸ Copies of the excerpted manuals are attached as exhibits to ECF 442, Relator Opp’n to Def. Mot. to Dismiss Third Am. Compl. Exhibit A is the 1968 manual; Exhibit B is the 1981 manual; and Exhibit C is the 1989 manual.

c. Importance of Allina to this False Claims Act Case

Having summarized the regulatory landscape and the history of CMS’s time-based framework for determining eligibility for inpatient status, discussion of the Supreme Court’s Allina decision is now relevant. Allina involved a new Medicare payment formula posted by CMS to its website that had the effect of substantially reducing payments to hospitals that served low-income patients. 139 S. Ct. at 1808. In a 7–1 decision, the Supreme Court invalidated the policy, holding that CMS’s failure to give notice and a chance to comment was fatal under 42 U.S.C. § 1395hh(a)(2). Id. at 1817.

Allina engaged in a textual analysis to determine the contours of what establishes a “substantive legal standard” under Section 1395hh(a)(2). Id. at 1811-14. The Supreme Court began its discussion by noting that the Medicare Act does not contain a definition for Section 1395hh(a)(2)’s phrase “substantive legal standard,” nor does a definition appear anywhere else in the United States Code. Allina, 139 S. Ct. at 1810. Allina’s close adherence to the text of the Medicare Act led the Supreme Court to conclude that a “substantive legal standard” triggering notice and comment under the Medicare Act is distinct from the Administrative Procedure Act (“APA”)’s “substantive rule” standard. Id. at 1814.

The significance of Allina’s distinction between “substantive legal standards” under the Medicare Act and “substantive rules” under the APA is that the Supreme Court explicitly left open the possibility that interpretive rules¹⁹—specifically excluded from the definition of “substantive rules” under the APA—could trigger a requirement for notice and comment under the Medicare Act. Id. at 1814; see also Select Specialty Hosp.-Denver, Inc. v. Azar, 391 F. Supp. 3d 53, 67

¹⁹ An interpretive rule is defined as a rule which “merely clarif[ies] or explain[s] existing law or regulations.” Am. Ambulance Serv. of Pennsylvania, Inc. v. Sullivan, 911 F.2d 901, 907 (3d Cir. 1990) (quoting Powderly v. Schweiker, 704 F.2d 1092, 1098 (9th Cir. 1983)).

(D.D.C. 2019) (“As a result [of Allina], in some circumstances CMS [will] not be obligated to conduct notice-and-comment rulemaking under the APA but is nonetheless required to do so under the Medicare Act.”); Yale New Haven Hosp. v. Azar, No. 18-1230, 2019 WL 3387041, at *7 (D. Conn. July 25, 2019) (“The Allina Court held that the notice and comment requirement extends, at least in some cases, to informal statements of policy and interpretive rules.”); cf. Memorandum from Attorney Gen. to All Components (Nov. 16, 2017) (“[G]uidance may not be used as a substitute for rulemaking and may not be used to impose new requirements.”). The Supreme Court declined to expound further on the metes and bounds of a “substantive legal standard” beyond concluding that the term is not synonymous with “substantive rule.” Allina, 139 S. Ct. at 1814

d. This Court Adopts the District of Columbia Circuit’s Definition of “Substantive Legal Standard”

Although Allina did not foreclose the possibility that an interpretive rule could be a “substantive legal standard” under the Medicare Act, the Supreme Court stopped short of providing a brightline definition. Id. Instead, the Court held that “[o]ther questions about the statute’s meaning can await other cases.” Id. The Third Circuit has not adopted a definition of “substantive legal standard,” and the only court in this district to confront the question did not have the benefit of the Supreme Court’s guidance in Allina.²⁰ Only one court of appeals, the District of Columbia Circuit, has articulated a definition for “substantive legal standard.”

According to the District of Columbia Circuit, the term substantive legal standard “at a minimum includes a standard that creates, defines, and regulates the rights, duties, and powers of

²⁰ The district court opinion considering this question, Wills v. Burwell, 306 F. Supp. 3d 684 (E.D. Pa. 2018) (Robreno, J.), involved an agency’s denial of a request to enroll in Medicare as a hospital. Id. at 687. Judge Robreno found that the Medicare Act’s notice and comment requirement did not apply “[b]ecause [the statement of policy at issue] [wa]s an interpretive rule and not a substantive rule” and therefore granted summary judgment for HHS. Id. at 692. Following the grant of summary judgment in favor of HHS in Wills, the case was appealed to the Third Circuit. However, the appeal was dismissed pursuant to FED. R. APP. P. 42(b), so the Third Circuit has not yet opined on the proper definition of “substantive legal standard.” (No. 18-1594, Document No. 003113088280, Nov. 16, 2018.)

parties.” Allina Health Servs. v. Price, 863 F.3d 937, 943 (D.C. Cir. 2017). Notably, the District of Columbia Circuit’s formulation was the very definition that the Supreme Court stated it was neither adopting nor rejecting. See Allina, 139 S. Ct. at 1814 (“We need not, however, go so far as to say that the hospitals’ interpretation, adopted by the court of appeals, is correct in every particular.”).

This Court adopts the District of Columbia Circuit’s definition for “substantive legal standard” and will assess the Medicare Act’s notice and comment requirement as it applies to the 24-hour policy accordingly.

e. Application

The determinative issue in this Court’s Allina analysis is whether the 24-hour policy referenced in the 1989 Manual and its predecessors is a “substantive legal standard” within the scope of Section 1395hh(a)(2). If so, then Relator’s Phase 1 claims fail as a matter of law, because it is undisputed that the 24-hour policy did not go through notice and comment as required by Section 1395hh(a)(2) for substantive legal standards. Applying the definition elucidated by the District of Columbia Circuit, it is clear that the 24-hour policy contained in the CMS manual is a “substantive legal standard” and therefore required notice and comment rulemaking procedures.

Case law applying the District of Columbia Circuit’s formulation of the definition for “substantive legal standard” illuminates a distinction between, on the one hand, rules that determine reimbursement and, on the other, statements that set forth enforcement policies. If a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a “substantive legal standard” under the Circuit’s definition. Conversely, if a policy does not affect the authority of CMS, but simply provides instructions for enforcement, it is more likely not to be

characterized as a “substantive legal standard.” Three cases—all applying the Circuit’s definition of “substantive legal standard”—explore the contours of this distinction.

Two of these cases found that, because the policies at issue affected the applicable reimbursement regime, the policies were “substantive legal standards” under the Medicare Act. In the District of Columbia Circuit’s Allina opinion, the Circuit held that the Medicare payment fractions at issue were “substantive legal standards” under its definition, because the formulae “determin[ed] how much the hospitals [would] be reimbursed.” Allina, 863 F.3d at 943. Similarly, in Select Specialty, a district court for the District of Columbia applied the Circuit’s definition of “substantive legal standard” to a CMS policy (the “must-bill” policy) that required hospitals to bill state Medicaid before seeking federal reimbursement. 391 F. Supp. 3d at 61. Select Specialty concluded that the must-bill policy was a “substantive legal standard” because it “essentially changed the eligibility criteria for reimbursement under the Medicare Act.” Id. at 69.

The last of the cases applying the Circuit’s definition found that the policy at issue, which merely provided instructions to direct enforcement, was not a “substantive legal standard” under the Medicare Act. In Clarian Health West, LLC v. Hargan, 878 F.3d 346 (D.C.C. 2017), the Circuit applied its definition to a policy expressed in a manual that provided criteria to guide healthcare insurers in selecting hospitals for reimbursement reconciliation. Clarian found that this policy was not a “substantive legal standard” because it “merely set forth an enforcement policy that determines when [private healthcare insurers] will report hospitals for reconciliation [to adjust reimbursement received].” Id. at 378-79. According to the Clarian court, in finding that the policy was not a substantive legal standard, the “important point [was] that the agency maintain[ed] the same authority ... that it had prior to the adoption of the Manual instructions.” Id. at 378.

It is evident that, in this case, the 24-hour policy must be included within the District of Columbia Circuit’s definition for substantive legal standard. Just as the respective policies in Allina and Select Specialty were “substantive legal standards” under the Circuit’s definition because they determined entitlement to reimbursement, here the 24-hour policy delineates the circumstances in which a hospital is entitled to higher inpatient reimbursement.

In other words, the 24-hour policy, though only expressed in CMS manuals, “affects a hospital’s right to payment” because it sets the standard by which a hospital’s entitlement to the higher reimbursement rate for inpatient claims is assessed. Allina, 139 S. Ct. at 1811. Therefore, the 1989 Manual which, for the first time, clearly established the 24-hour policy, is a “substantive legal standard” under the Medicare Act. It follows, then, that the law required advance public notice and an opportunity to comment prior to implementation of the 24-hour policy. Because there was no such public notice or a chance to comment, the policy cannot withstand scrutiny under Allina’s interpretation of the Medicare Act.

Relator argues that Allina is not controlling because the 24-hour policy simply “provided guidance regarding how to implement the preexisting ‘overnight stay’ standard,” which was contained in the 1968 Manual that predated the 1987 adoption of Section 1395hh. (Relator Opp’n to Government Mot. to Dismiss at 24.) Therefore, according to Relator, the 24-hour policy of the 1989 manual is not subject to Section 1395hh(a)(2)’s notice and comment requirement, because it merely interprets the preexisting standard of the 1968 manual, which predated the enactment of the Medicare Act’s notice and comment provision.²¹ Said differently, Relator’s theory is that the

²¹ Relator does not argue that Section 1395hh(a)(2) is inapplicable because the operative guidance is the 1981 Manual—which was adopted prior to enactment of the notice and comment requirement—and that therefore the notice and comment requirement is inapplicable. Such an argument would be both factually and legally unpersuasive. Factually, the record indicates that the 24-hour policy was included in the 1989 Manual (adopted after the 1987 notice and comment amendment). Legally, because “[t]here is no indication in the language or the legislative history of ... [Section] 1395hh(a)(2) that Congress intended the statute to have retroactive application,” Section 1395hh(a)(2) would

24-hour policy was simply a gloss on the 1968 guidance, and that because the 1968 guidance was published nineteen years before the enactment of Section 1395hh in 1987, the notice and comment requirement of Section 1395hh(a)(2) cannot apply.

While Relator characterizes the 24-hour policy as an interpretation of the prior standard, it is better viewed as a “gap-filler” in the Medicare Act’s reimbursement regime. Allina explicitly held that “when the government establishes or changes an avowedly ‘gap’-filling policy, it can’t evade its notice-and-comment obligations under [Section] 1395hh(a)(2).” 139 S. Ct. at 1817. Therefore, Relator cannot justify CMS’s failure to provide notice and comment for the 24-hour policy by characterizing it as mere guidance on a preexisting standard when the policy, in substance, is a gap-filling exercise prompted by the ambiguity of the prior policy. See Select Specialty, 391 F. Supp. 3d at 70 (finding that the agency impermissibly circumvented the notice and comment requirement because it did not “argue that [the policy was] compelled by the Medicare Act itself;” instead, the policy was simply “filling a ‘gap’ as to how best to administer the Medicare program”). Since the 24-hour policy was contained in agency manuals that had not been promulgated pursuant to notice and comment, Allina compels the conclusion that there can be no FCA liability on Relator’s Phase 1 claims.

f. This Court Rejects Relator’s Argument that Defendant Has Liability Under Statutes Not Implicated by Allina

Relator also argues that summary judgment under Allina is not warranted because his Phase 1 claims rest on violations of “several other entirely distinct Medicare requirements, all set forth in statutes or formal requirements.” (Relator Opp’n to Government Mot. to Dismiss at 19.) According to Relator, even if the lack of notice and comment justifies summary judgment on

not apply retroactively and invalidate the 1981 Manual. Cedars-Sinai Med. Ctr. v. Shalala, 939 F. Supp. 1457, 1463 (C.D. Cal. 1996).

Relator's Phase 1 claims that are based on Defendant's violation of the 24-hour policy, the Phase 1 claims nonetheless should survive because his case also involves violations of separate regulations promulgated pursuant to notice and comment to which Allina does not apply. As one example of this theory, Relator references the declaration of Richard Baer, Medical Director for Medicare's Recovery Audit Program from 2009–2014. (Id. at 32; ECF 555, Relator Suppl. Memorandum in Supp. of Mot. to Dismiss Relator's Third Am. Compl. at 4.) In his declaration and accompanying report, Baer purports to explain "the ways in which [Defendant] for years violated both statutory requirements and Medicare regulations governing hospital Utilization Review ("UR") Committees." (Relator Opp'n to Government Mot. to Dismiss, Ex. 43 ¶ 6.) Relator argues, therefore, that even if Allina precludes FCA liability for Defendant's alleged violation of the 24-hour policy, there nonetheless may be liability for violation of the UR regulations.

The Court rejects Relator's argument as unsubstantiated, if not waived, by pretrial proceedings. It is clear from Relator's selection of specific claims for the bellwether trial that he was relying on the time-based reimbursement guidance for his Phase 1 claims. Even if liability under the other statutes referenced by Relator and Baer could be a lingering issue on summary judgment, the Court considers it waived because Relator did not meaningfully litigate these violations. Relator's contention that he is pursuing, in addition to violations of the CMS time-based guidance, violations of entirely independent regulatory requirements is inconsistent with the way he has prosecuted this case. Therefore, his attempt to undermine the applicability of Allina does not convince the Court.

In summary, the 24-hour policy—the time-based standard for reimbursement contained in the 1989 Manual—is a "substantive legal standard" under the Medicare Act and therefore required

notice and comment rulemaking. Because CMS did not go through the notice and comment process with respect to the 24-hour policy, there can be no FCA liability on the Phase 1 claims.

3. Lack of Materiality Under Escobar May Warrant Summary Judgment on Phase 1 Claims and Two Midnight Claims

There is no evidence in this case that CMS ever—either during Phase 1 or during the Two Midnight period—refused to pay a reimbursement claim that Defendant certified. Therefore, Defendant may be entitled to summary judgment on the Phase 1 claims and the Two Midnight claims because the Court has substantial reason to doubt Relator’s ability to establish that Defendant’s alleged misconduct was “material” to the Government’s decision to provide reimbursement.²² Although any granting of summary judgment on the Two Midnight claims would be premature because discovery was not completed on the second phase of the case, this section discusses the Court’s view on the FCA’s materiality standard as it applies to Relator’s post-October 1, 2013 claims.

A violation must be material to the Government’s payment decision for FCA liability to attach. See Universal Health Servs., Inc. v. Escobar, 136 S. Ct. 1989, 2001 (2016) (“Under the [False Claims] Act, the misrepresentation must be material to the other party’s course of action.”) (emphasis added). The FCA defines materiality as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4). The FCA’s materiality requirement is “demanding” and “rigorous.” Escobar, 136 S. Ct. at 2003;

²² The Court notes that although Relator’s Phase 1 claims may ultimately fail for want of materiality, the record reveals a dispute as to whether Defendant’s representations to CMS were material to the Government’s decision to reimburse the Phase 1 claims. Specifically, Relator argues that a white paper Defendant submitted to the Government outlining its procedure for certifying medical necessity, (Relator Opp’n to Government Mot. to Dismiss, Ex. 38), did not align with principles in internal training materials that Defendant provided to its employees, (*id.* Ex. 50). See also Sept. 25, 2019 Hr’g Tr. 39:16-25; 40:1-25; 41:1-20) (discussing discrepancy); Relator Opp’n to Government Mot. to Dismiss at 34 (“[T]he ... whitepaper provided to [the DOJ] ... was radically different from the Guidance Documents [Defendant] provided to its PAs to determine hospital status.”). Therefore, in finding that summary judgment is proper on the Phase 1 claims, the Court presently relies only on the Allina rationale, but does not foreclose reliance on Escobar if there is ever a need to resume the analysis of the factual record of this case.

2004 n.6; see also Petratos v. Genentech Inc., 855 F.3d 481, 492 (citing cases recognizing that Escobar imposed a “heightened materiality standard”). A misrepresentation is not material “merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition for payment;” simply because “the Government would have the option to decline to pay if it knew of the defendant’s noncompliance;” or if the “noncompliance is minor or insubstantial.” Escobar, 136 S. Ct. at 2003. The purpose of this exacting standard is to ensure the FCA is not used as “an all-purpose antifraud statute” or “a vehicle for punishing garden-variety breaches of contract or regulatory violations.” Id.

The Escobar court provided guidance to assist lower courts in analyzing FCA materiality. Escobar instructed that “the Government’s decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive,” and that “proof of materiality can include ... evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.” Id. Equally, the Escobar court made clear that “if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.” Id. at 2003-04.

Applying the Escobar framework, the Court doubts whether Relator can prove the elements of his FCA case as to the Two Midnight phase because he will not be able to establish that Defendant’s alleged noncompliance was material to the Government’s decision to pay.²³ Relator avers that Defendant’s “false and fraudulent statements [were] material to the Government’s

²³ The Court’s conclusion in denying Defendant’s Motion to Dismiss the Supplemental Complaint that “the detailed allegations ... regarding Relator’s experience at client hospitals plausibly allege that Defendant’s false inpatient certifications were material to the [G]overnment’s decision to pay Medicare claims in the period 2012–15” is not to the contrary. (ECF 228, Memorandum re: Mot. to Dismiss Suppl. Compl. at 14.) Relator needs more than plausible allegations to survive summary judgment, and for the reasons discussed, the Court finds that he likely falls short of Escobar’s demanding materiality standard.

decision to pay because they were capable of influencing or did influence the Government's decision to pay." (Third Am. Compl. ¶ 340.) However, even though discovery has not been completed on the Two Midnight phase, the Government's actions in this litigation and the Government's actions in regard to Defendant overwhelmingly suggest a lack of materiality.

First, the Government's actions in this case—declining to intervene and moving for dismissal—are probative of the lack of materiality of Relator's Two Midnight claims. Post-Escobar, numerous federal courts have found insufficient FCA materiality where the government investigated a relator's allegations but chose not to intervene or otherwise address the defendant's allegedly improper behavior. For example, in Cressman v. Solid Waste Services, Inc., the court found "the Department of Justice's declination to intervene or take any action against Defendant" relevant to the materiality inquiry and supportive of the conclusion that this element of relator's FCA claim was lacking. No. 13-5693, 2018 WL 1693349, at *6 (E.D. Pa. Apr. 6, 2018) (Quiñones Alejandro, J.); see also Petratos, 855 F.3d at 490 ("[T]he Department of Justice has taken no action against [Defendant] and declined to intervene in this suit."); United States v. Sanford-Brown, Ltd., 840 F.3d 445, 447 (6th Cir. 2016) (affirming grant of summary judgment based on lack of materiality where the government investigated the allegedly fraudulent conduct and "concluded that neither administrative penalties nor termination was warranted").

Similarly here, the Government declined to prosecute Relator's claims after investigating his Complaint for nearly two years. In point of fact, the Government went even further than declining to intervene—it moved to dismiss Relator's claims entirely "[a]fter lengthy and careful consideration." (Government Reply Memorandum at 1.) The Government's apparent view that Relator's claims are not worthy of even private enforcement is relevant because it underscores the conclusion that Defendant's alleged fraud was not material in the eyes of the payor and ultimate

beneficiary of Relator's claims—the Government. Cf. Escobar, 136 S. Ct. at 1995 (excepting “minor or insubstantial” noncompliance from FCA materiality). Moreover, Relator does not allege that the Government initiated proceedings or took other action against Defendant.²⁴ See Cressman, 2018 WL 1693349, at *6 (explaining that the government's failure to take action against FCA defendant “show[ed] that the alleged misrepresentations ... were not material”).

Second, despite the Government's knowledge of the alleged fraudulent scheme from its extensive involvement in this litigation, there is no evidence that, either during Phase 1 or during the Two Midnight period, the Government ever refused to pay a claim certified by Defendant. Indeed, Relator acknowledges that Defendant's client hospitals continue to receive reimbursement for claims it certifies. See Third Am. Compl. ¶ 356 (“[Defendant's] fraud is an ongoing scheme that continues up to the present.”). Escobar held that proof “the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position” is “strong evidence” that the noncompliance was not material. Escobar, 136 S. Ct. at 2003-04. Based on this teaching, the Government's decision not to reject reimbursement claims in this case—despite full knowledge of Relator's theory of the alleged fraud since July 2012 when Relator first filed his complaint—confirms that Defendant's noncompliance is likely not material under the FCA. See Kelly v. Serco, Inc., 846 F.3d 325, 334 (9th Cir. 2017) (finding that relator “failed to establish a genuine issue of material fact regarding materiality” on FCA claim where the government continued to make payment after learning of alleged noncompliance); Cressman, 2018 WL 1693349, at *6 (finding that “record evidence show[ing] that the government ... continued to pay ... even after Plaintiff filed the underlying suit

²⁴ Attached to Relator's opposition to the Government's Motion to Dismiss is the declaration of Chad Walker, an attorney at counsel of record for Relator. (Relator Opp'n to Government Mot. to Dismiss Ex. 2.) In the declaration, Walker describes settlements between the DOJ and fourteen of Defendant's clients. (Id. ¶ 3(a)–(n).) Tellingly, however, the declaration does not indicate that the DOJ has pursued action directly against Defendant.

and after the Department of Justice investigated the allegations ... and declined to intervene” demonstrated lack of materiality).

The Third Circuit recognized that “[b]ecause the False Claims Act was passed to protect the federal treasury, ... and since the Government decides on payment, ... it is the Government’s materiality decision that ultimately matters.” Petratos, 855 F.3d at 492 (emphasis added). Because the Government’s actions—declining to intervene or take other action against Defendant, moving to dismiss Relator’s case entirely, and continuing to pay claims—signal that they do not view the alleged conduct to be material, summary judgment on the Two Midnight claims may be appropriate.

IV. CONCLUSION

For the foregoing reasons, the Government’s Motion to Dismiss is **GRANTED**. The Court also finds that, independent of dismissal based on the Government’s motion, summary judgment is properly granted to Defendant on the Phase 1 claims.

An appropriate order follows.